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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,723	01/28/2002	Sigfrid Schwarz	1815	5696

7590 12/12/2002
Striker Striker & Stenby
103 East Neck Road
Huntington, NY 11743

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/12/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/937,723

Applicant(s)
Schwarz et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 28, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-15, 20, and 21 is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 & 7 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 10-21 are pending in this application.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The scope of the method claims is not adequately enabled solely based on the antioxidative activity provided in the specification. The claim language includes diseases that are known and those that are yet to be discovered, for which there is no enablement. First, the instant claims cover 'diseases' that are known to exist and those that may be discovered in the

Art Unit: 1624

future, for which there is no enablement provided. The use disclosed in the specification is as pharmaceutical therapeutic agents having selective antioxidative activity, useful to treat a diverse list of diseases, which include CNS diseases, degenerative neurological diseases, etc. There are no test assays or results provided to show that the compounds exhibit the antioxidative activity. A state of the art reference, Bhavnani et al. (PubMed Abstract enclosed) states that “the *in vivo* metabolism of ring B unsaturated estrogens is complex” thus expressing the uncertainties of pharmacological mechanisms and pharmacokinetic characteristics of equilenin derivatives, see the abstract. Therefore, there is nothing in the disclosure regarding the activity of the compounds *in vitro* or *in vivo* and further, showing that such activity correlates to the treatment of the diverse disorders of the instant claims.

The disorders encompassed by the instant claims include central nervous system disorders, neurodegenerative diseases, etc., some of which have been proven to be extremely difficult to treat. Further, there is no reasonable basis for assuming that the various compounds embraced by the claims will all share the same physiological properties based on their structural dissimilarities and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Further, the specification provides that the diseases include degenerative neurological diseases (see page 3) which covers diverse disorders such as Alzheimer’s disease, dementia, hereditary cerebellar ataxias, paraplegias, syringomyelia, phakomatoses, and much more. In fact, Layzer, Cecil Textbook of Medicine (article enclosed), states that “some degenerative diseases

Art Unit: 1624

are difficult to classify because they involve multiple anatomic locations” (see page 2050). For example, Alzheimer’s disease has traditionally been very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents. See e.g., the Cecil Textbook of Medicine, 20th edition (1996), Vol. 2, wherein it is stated that “[t]here is no cure for Alzheimer’s disease, and no drug tried so far can alter the progress of the disease.” (pg. 1994). Also, see Gilgun-Sherki et al. (PubMed Abstract enclosed), regarding antioxidant as therapeutic agents, states that “the therapeutic use of most of these compounds is limited since they do not cross the blood brain barrier (BBB)”. Further, the reference states that “none of the currently available antioxidants have been proven efficacious in a large scale controlled study”, thereby establishing the unpredictability of the therapeutic utility associated with antioxidants.

Further, the list of the diseases in the specification includes asthma (see page 3, line 6) and Branisteanu et al. (PubMed Abstract enclosed) regarding the efficacy of antioxidants in the treatment of bronchial asthma, state that “further investigations are needed”. (Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements).

The instant claims 16-17 are drawn to ‘A method of **geroprophylaxis**...’, first it is not clear what is intended by this term (see the rejection under 112, second paragraph). The term ‘prophylaxis’ means ‘preventive treatment’ of the diseases, and therefore, the instant claim language embraces disorders not only for the treatment, but for “prevention” which is not remotely enabled. Based on the antioxidative activity stated for the compounds, the instant

Art Unit: 1624

compounds are disclosed to be useful in the “prevention” of central nervous system disorders, stroke, degenerative neurological diseases, etc., for which applicants provide no competent evidence. “To prevent” actually means *to anticipate or counter in advance, to keep from happening etc.* (as per Webster's II Dictionary) and therefore it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the ‘prophylactic or preventive’ effect. It is inconceivable from the instant disclosure, how the instantly claimed compounds can be correlated not only to the treatment, but also to ‘**prophylaxis**’ of the various disorders associated with the stated activity. Further, there is no evidence on record which demonstrates that antioxidative activity is recognized in the art as being reasonably predictive of success in any of the contemplated areas of ‘prevention’. Such a reasonable correlation is necessary to demonstrate such utilities. See *Ex parte Stevens*, 16 USPQ 2d 1379 (BPAI 1990); *Ex parte Busse et al.*, 1 USPQ 2d 1908 (BPAI 1986) (the evidence must be accepted as “showing” such utility, and not “warranting further study”).

Part of the difficulty of developing drugs effective for **prophylaxis** of central nervous system disorders, degenerative neurological diseases, etc. lies in the lack of understanding as to why people come down with these disorders and the numerous causes of these disorders.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the

Art Unit: 1624

unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claims 16-17, the term “geroprophylaxis” is not clear. It is not understood what is intended by this term.
2. In claims 18-19, line 2, the phrase “diseases or organs or tissues caused, at least in part, by oxygen radicals” is not understood. It is not clear what is intended by ‘organs caused by oxygen radicals’ or ‘tissues caused by oxygen radicals’.

Allowable Subject Matter

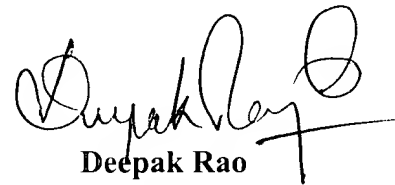
Claims 10-15 and 20-21 are allowed. The closest reference of record, Künzer et al., teaches equilenin derivatives, see compounds 9-12 in page 2329, however, does not teach or fairly suggest fluorine or oxygen function at 11-position.

Art Unit: 1624

Receipt is acknowledged of the Information Disclosure Statements and copies are enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Deepak Rao
Primary Examiner
Art Unit 1624

December 11, 2002